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| PARK, EDWARD | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/790,478 | CHEN ET AL. | |
| | Examiner | Art Unit | |
| | EDWARD PARK | 2624 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Amendment*

1. This action is responsive to applicant's amendment and remarks received on 2/24/09. Claims 1-17 are currently pending.

### *Response to Arguments*

2. Applicant's arguments filed on 2/24/09, in regards to claim 1, have been fully considered but they are not persuasive. Applicant argues that Adler does not disclose a generalized R and G colors or non-luminance generalized R and G colors (see pg. 7, second paragraph – last paragraph). This argument is not considered persuasive since the limitation only calls for utilizing generalized R and G colors which is shown as seen in the applicant's arguments, within Adler, paragraph [0023], where hue H is calculated and takes into account color changes from red to yellow to green to cyan to blue to magenta and back to red again also, V is a measure of relative intensity of color, representing brightness of red, blue and green. Examiner notes that the cited limitation only calls for a generalized R and G colors which is interpreted as any colors that contain R and G components which are disclosed by Adler. Furthermore, due to the 112 rejection of the newly added limitation, non-luminance generalized R and G colors, is not given weight since it is not supported within the specification and deemed as new matter. In arguendo, the calculation of the hue discloses the limitation within paragraph [0023], which determines if the color changes from red to yellow to green to cyan to blue to magneta and back to red again.

Regarding claims 16, 17, applicant argues that the claims are allowable due to the same reasons as stated within claim 1 (see pg. 8, second paragraph). This argument is not considered persuasive since claim 1 stands rejected and the arguments and rejection can above and below, respectively.

Regarding claims 2-15, applicant argues that the claims are allowable due to the dependency and for the same reasons as stated within claim 1 (see pg. 8, third paragraph). This argument is not considered persuasive since claim 1 stands rejected and the arguments and rejection can be seen above and below, respectively.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. **Claims 1, 16, 17** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added limitation as seen in claims 1, 16, 17, "non-luminance", is not recited or mentioned in the specification, as originally filed, and deemed to be new matter that is not supported within the specification. Applicant is advised to correct the claim language appropriately to overcome the new matter rejection in accordance with the original disclosure.

***Claim Rejections - 35 USC § 101***

5. In response to applicant's amendment of claims 16, 17, the amendment does not overcome the 101 Tied to Criteria and the rejection of claims 16 and 17 remain as seen below.

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

**Claims 16, 17** are rejected under 35 U.S.C. 101 as not falling within one of the four statutory categories of invention. The Federal Circuit[1], relying upon Supreme Court precedent[2], has indicated that a statutory "process" under 35 U.S.C. 101 must (1) be tied to a particular machine or apparatus, or (2) transform a particular article to a different state or thing. This is referred to as the "machine or transformation test", whereby the recitation of a particular machine or transformation of an article must impose meaningful limits on the claim's scope to impart patent-eligibility (See *Benson*, 409 U.S. at 71-72), and the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity (See *Flook*, 437 U.S. at 590"). While the instant claim(s) recite a series of steps or acts to be performed, the claim(s) neither transform an article nor are positively tied to a particular machine that accomplishes the claimed method steps, and therefore do not qualify as a statutory process. That is, the method includes steps of capturing, diagnosing, signaling, etc. is of sufficient breadth that it would be reasonably interpreted as a series of steps completely performed mentally,

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[1] *In re Bilski*, 88 USPQ2d 1385 (Fed. Cir. 2008).

[2] *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876).

verbally, or without a machine. The cited claims do not positively recite any structure within the body of the claim which ties the claim to a statutory category. Furthermore, the examiner suggests that the structure needs to tie in the basic inventive concept of the application to a statutory category. Structure that ties insignificant pre or post solution activity to a statutory category is not sufficient in overcoming the 101 issue. Additionally, the limitations do not claim data that represents a physical object or substance, the data representing the physical object is not present and therefore can not be modified by the process in a meaningful or significant manner, and no meaningful and significant external, non-data depiction of a physical object or substance is produced. Thus, the limitations do not satisfy the transformation test.

[1] *In re Bilski*, 88 USPQ2d 1385 (Fed. Cir. 2008).

[2] *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876).

### *Claim Rejections - 35 USC § 103*

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. **Claims 1-11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Yokoi et al. (US 6,951,536 B2) with Adler et al (US 2002/0177779 A1), and further in view of Nemeth et al. (WO 01/99703 A2).

Regarding **claims 1 and 11**, Yokoi teaches an automatic notification and remote access method for diagnosing real-time in vivo images from a location remote from one or more in vivo video camera systems, comprising the steps of:

a) capturing multiple sets of real-time in vivo images ("set of images captured inside the body"; Yokoi: col. 19, line 63-64) using the one or more in vivo video camera systems ("an image pickup device and an illumination device"; Yokoi: figure 4; col. 4, lines 65-67); and

g) routing the automatic notification including information on in vivo camera travel distance in GI tract to remote recipient(s) (see col. 14, lines 57-67; col. 15, lines 1-5; data obtained are temporarily accumulated in memory located inside the capsule and then transmitted by the transmission-receiving circuit 30 and antenna 31 to a receiver such as the external unit 5 located outside the body by comparing the data obtained by the receiver with the standard values, and to determine the capsule advancing position or state);

Yokoi does not teach forming an examination bundlette, image processing in vivo images in the examination bundlette in a generalized R and G color space for robust disease detection; using color image processing algorithms to automatically diagnose one or more abnormalities in one or more of the in vivo images in the generalized R and G color space using non-luminance generalized R and G colors in the in vivo images; signaling an alarm, receiving an automatic notification, executing one or more diagnosing tasks and applying image processing algorithms to an image portion of the examination bundlette.

Adler, in the same field of endeavor, teaches image processing in vivo images in the examination bundlette in a generalized R and G color space for robust disease detection and using color image processing algorithms to automatically diagnose one or more abnormalities in

one or more of the in vivo images in the generalized R and G color space using non-luminance generalized R and G colors in the in vivo image and applying image processing algorithms to an image portion of the examination bundlette (see paragraph [0009], [0023], [0030], [0031]; detecting colorimetric abnormalities in a gastrointestinal tract. The capsule includes an image-receiver for receiving images from the gastrointestinal tract, and a processor for generating a probability indication for presence of calorimetric abnormalities by comparing color content of the images to at least one reference value; Each test sample T is located within a coordinate system represented by the following variables: hue H, saturation S and value V. Hue H represents a number related to the dominant wavelength of the color stimulus, and varies from 0 to 1 as the color changes from red to yellow to green to cyan to blue to magenta and back to red again. Saturation S corresponds to color purity, and in the case of a pure color is equal to 100%. Value V is a measure of relative intensity of color, representing brightness of red, blue and green (RBG). A distance vector r(B,T) between test sample T and an ideal pathology sample B is calculated. Another distance vector r(R,T) between test sample T and a reference sample of healthy tissue R is calculated. The relationship of distance vector r(B,T) and distance vector r(R,T) is calculated. Each test sample T is classified based on the relationship between distance vector r(B,T) and distance vector r(R,T)). Examiner notes that the element, "for robust disease detection", implies intended use and will not be given weight in regards to the claim limitations of claim 1. Furthermore, "robust disease detection", differs from diagnose of abnormalities since disease is a malignant/unwanted medical condition while an abnormality in the context of the claim is a condition that is not normal.

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the Yokoi reference to color image process/processing algorithms to the examination bundlette as suggested by Adler, in order to detect a colorimetric abnormality that may indicate a pathological condition, such as bleeding, blood clots, polyps, lesion, ulcerations, angiodisplasia, and telagecasia (see paragraph [0022]).

Nemeth, in the same field of "monitoring medical data" (Nemeth: pg. 1) teaches:

b) forming an in vivo video camera system examination bundlette of a patient that includes the real-time ("real time"; Nemeth: pg. 9, line 20) captured in vivo images for each of the one or more in vivo video camera systems ("medical data relating to physiological or biological status of a patient includes all data relating to the physical condition and composition of the patient"; Nemeth: figure 1, numeral 10; pg. 14, lines 19-21). Images fall under the category of medical data since it is well known in the art that data transcribed in the form of medical images are essential for examination purposes.

e) signaling an alarm provided that the one or more abnormalities in the examination bundlette have been detected ("analyze the medical data and provide the third party with an alert if the medical data meets the established conditions for an alert"; Nemeth: figure 2, numeral 58; pg. 32, lines 17-18);

f) receiving an automatic notification via one or more unscheduled alarming messages from one or more randomly located in vivo video camera systems ("store the medical data and other related information for review by third party" Nemeth: figure 2, numeral 64); and

h) executing one or more diagnosing tasks corresponding to the automatic notification responsive to the alarming signaling time ("third party may instruct the patient to take certain remedial measures"; Nemeth: figure 2, numeral 70; pg. 27, lines 30-32; pg. 28, lines 1-16).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the Yokoi with Adler combination as mentioned above to utilize forming an in vivo video camera system examination bundlette as suggested by Nemeth, in order to further enhance the treatment of a patient by allowing all data to be accessible at once by any party.

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the Yokoi with Adler combination to automatically detect one or more abnormalities in the examination bundlette based on predetermined criteria for the patient as suggested by Nemeth, in order "analyze and respond to the medical data in a timely matter" (Nemeth: pg. 8, lines 11) and to reduce human errors in manual detection.

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the Yokoi with Adler combination to signal, receive, and route an alarm/message, and to execute one or more diagnosing tasks as suggested by Nemeth, in order to allow "the third party to quickly review the medical data and other related information, to provide instructions for any necessary remedial action" (Nemeth: pg. 33, lines 3-5) and to effectively treat the patient's illness or ailment.

Regarding **claim 2**, the rejection of claim 1 is incorporated and Yokoi further discloses wherein the unscheduled alarming messages correspond to a detection ("conducting examination"; Yokoi: col. 2, lines 5-7) of an abnormality found in the patient's GI tract ("inside of somatic cavities"; Yokoi: figure 1, numeral 16A, B; col. 2, lines 5-7).

Regarding **claim 3**, the Yokoi, Adler, with Nemeth combination teaches the elements disclosed in claim 1. The Yokoi, Adler, with Nemeth combination as mentioned above in claim 1, does not teach where in the automatic notification includes patient metadata describing the patient's medical history and location. Nemeth further teaches where in the automatic notification includes patient metadata describing the patient's medical history and location ("position of the patient .... underlying medical data"; Nemeth: pg. 10, lines 5-15). It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the Yokoi, Adler, with Nemeth combination to include patient metadata describing the patient's medical history and location as suggested by Nemeth, in order to have all related patient information bound together to effectively treat the patient's illness or ailment.

Regarding **claim 4**, the rejection of claim 1 is incorporated and Yokoi further discloses wherein the one or more randomly located in vivo video camera systems are located in different geographic regions of a country and/or a continent ("patient is in a remote location far from a hospital"; Yokoi: fig. 36A, B; col. 25, lines 20-31).

Regarding **claim 5**, the Yokoi, Adler, with Nemeth combination teaches the elements disclosed in claim 1. The combination does not teach providing a communication channel and providing the remote recipient(s) with the automatic notification of a detected GI tract abnormality. Nemeth further teaches wherein the step of routing the automatic notification to the remote recipient(s), further comprises the steps of:

providing a communication channel to the remote recipient(s) ("medical data is transmitted via the internet such that the third party can view the medical data"; Nemeth: pg. 10, lines 24-25); and

providing the remote recipient(s) with the automatic notification of a detected GI tract abnormality ("transmit an alert if it is determined that the medical data meets the conditions established for the generation of an alert"; Nemeth: pg. 10, lines 29-31).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the Yokoi, Adler, with Nemeth combination to provide a communication channel and automatic notification as taught by Nemeth, in order to allow "the third party to quickly review the medical data and other related information, to provide instructions for any necessary remedial action" (Nemeth: pg. 33, lines 3-5) and to effectively treat the patient's illness or ailment.

Regarding **claim 6**, the rejection of claim 1 is incorporated and Yokoi further discloses wherein the unscheduled alarming messages operate within a two-way messaging system ("cellular phones, internet"; Yokoi: fig. 36A, numeral 182; col. 25, lines 38-39).

Regarding **claim 7**, the rejection of claim 1 is incorporated and Yokoi further discloses wherein the remote recipient receives messages by utilizing a two-way messaging system ("cellular phones, internet"; Yokoi: fig. 36A, numeral 182; col. 25, lines 38-39).

Regarding **claim 8**, the rejection of claim 1 is incorporated and Yokoi further discloses wherein the remote access is accomplished by a communications network ("transmission may be conducted with other communications means such as cellular phone, internet"; Yokoi: fig. 36A, numeral 182; col. 25, lines 9-13, 35-39) for retrieving and/or sending the patient's in vivo images from multiple locations either inside or outside ("remote site"; Yokoi: col. 25, lines 9-13, 35-39) of a clinical environment ("remote location far from a hospital"; Yokoi: col. 25, lines 9-13, 35-39).

Regarding **claim 9**, the rejection of claim 1 is incorporated and Yokoi further discloses wherein the step of forming the examination bundlette, includes the steps of:

forming an image packet of the captured in vivo images of the patient ("image data … accumulated in memory"; Yokoi: col. 22, lines 11-13);

forming patient metadata ("memory storing the patient's data"; Yokoi: col. 22, lines 21); and

combining the image packet and the patient metadata into the examination bundlette ("when the image data are transmitted, the patient's data stored in the memory may be transmitted as header information of the image data"; Yokoi: col. 22, lines 20-25).

Regarding **claim 10**, the rejection of claim 1 is incorporated and Yokoi further discloses wherein the step of processing the examination bundlette, includes the steps of:

separating the in vivo images from the examination bundlette ("identification code may be recognized by the external unit and separated from the image data" Yokoi: col. 20, lines 43-44);

and processing the in vivo images according to selected image processing methods ("control circuit … conducts a comparative processing such as pattern matching of the captured image and the disease image read out from the disease database …"; Yokoi: figure 18; col. 19, lines 29-35).

9. **Claims 12-15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Yokoi et al. (US 6,951,536 B2), Adler et al (US 2002/0177779 A1), with Nemeth et al. (WO 01/99703 A2), and further in view of Kenet et al (US 5,836,872).

Regarding **claims 12-15**, Yokoi, Adler, with Nemeth combination discloses all elements as mentioned above in claim 1. The Yokoi, Adler, with Nemeth combination does not teach detecting one or more abnormalities based on predetermined image criteria for the patient; detecting one or more abnormalities based on predetermine image criteria for the patient employing image data transformation and detection; transforming image data for an image portion of the examination bundlette to a generalized color space; detecting one or more abnormalities by applying thresholding; and applying lower/higher thresholding or higher thresholding in the generalized image color space.

Kenet teaches detecting one or more abnormalities based on predetermined image criteria for the patient (Kenet: col. 16, lines 36-67; col. 17, lines 1-15); detecting one or more abnormalities based on predetermine image criteria for the patient employing image data transformation and detection (Kenet: col. 16, lines 36-67; col. 17, lines 1-15); transforming image data for an image portion of the examination bundlette to a generalized color space (Kenet: col. 16, lines 36-67; col. 17, lines 1-15); detecting one or more abnormalities by applying thresholding (Kenet: col. 16, lines 36-67; col. 17, lines 1-15); and applying lower and higher thresholding or higher thresholding in the generalized image color space (Kenet: col. 16, lines 36-67; col. 17, lines 1-15).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the Yokoi, Adler, with Nemeth combination to utilize image transformation and to detect abnormalities through thresholding as suggested by Kenet, in order to enhance the reliability, precision of the system in regards to detection of abnormalities.

10. **Claim 16** is rejected under 35 U.S.C. 103(a) as being unpatentable over Yokoi et al. (US 6,951,536 B2) with Adler et al (US 2002/0177779 A1), and further in view of Nemeth et al. (WO 01/99703 A2).

Regarding **claim 16**, Yokoi discloses a method comprising:

capturing a real-time in vivo images with a camera ("set of images captured inside the body"; Yokoi: col. 19, line 63-64); and relaying information on in vivo camera travel distance in GI tract (see col. 14, lines 57-67; col. 15, lines 1-5; data obtained are temporarily accumulated in memory located inside the capsule and then transmitted by the transmission-receiving circuit 30 and antenna 31 to a receiver such as the external unit 5 located outside the body by comparing the data obtained by the receiver with the standard values, and to determine the capsule advancing position or state).

Yokoi does not disclose automatically diagnosing an abnormality in a non-luminance generalized R and G color space in real-time in the in vivo images using R and G color image processing algorithms; and signaling an alarm with information on in vivo camera travel distance in GI tract in real-time when the abnormality is detected.

Adler, in the same field of endeavor, teaches automatically diagnosing an abnormality in a non-luminance generalized R and G color space in real-time in the in vivo images using R and G color image processing algorithms (see paragraph [0009], [0023], [0030], [0031]; detecting colorimetric abnormalities in a gastrointestinal tract. The capsule includes an image-receiver for receiving images from the gastrointestinal tract, and a processor for generating a probability indication for presence of calorimetric abnormalities by comparing color content of the images to at least one reference value; Each test sample T is located within a coordinate system represented

by the following variables: hue H, saturation S and value V. Hue H represents a number related to the dominant wavelength of the color stimulus, and varies from 0 to 1 as the color changes from red to yellow to green to cyan to blue to magenta and back to red again. Saturation S corresponds to color purity, and in the case of a pure color is equal to 100%. Value V is a measure of relative intensity of color, representing brightness of red, blue and green (RBG). A distance vector r(B,T) between test sample T and an ideal pathology sample B is calculated. Another distance vector r(R,T) between test sample T and a reference sample of healthy tissue R is calculated. The relationship of distance vector r(B,T) and distance vector r(R,T) is calculated. Each test sample T is classified based on the relationship between distance vector r(B,T) and distance vector r(R,T)).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the Yokoi reference to color image process/processing algorithms to the examination bundlette as suggested by Adler, in order to detect a colorimetric abnormality that may indicate a pathological condition, such as bleeding, blood clots, polyps, lesion, ulcerations, angiodisplasia, and telagecasia (see paragraph [0022]).

Nemeth, in the same field of "monitoring medical data" (Nemeth: pg. 1) teaches:

signaling an alarm in real-time when the abnormality is detected ("analyze the medical data and provide the third party with an alert if the medical data meets the established conditions for an alert"; "provide alerts, warnings and other information to third party will be informed, preferably in real time or near real time, of instances which the medical data meet certain predetermined conditions that merit the immediate attention of the third party; Nemeth: figure 2, numeral 58; pg. 32, lines 17-18; pg. 7, lines 24-28).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify Yokoi with Adler to automatically detect an abnormality and signal an alarm as suggested by Nemeth, in order "analyze and respond to the medical data in a timely matter" (Nemeth: pg. 8, lines 11) and to reduce human errors in manual detection.

11. **Claim 17** is rejected under 35 U.S.C. 103(a) as being unpatentable over Yokoi et al. (US 6,951,536 B2), Adler et al (US 2002/0177779 A1), with Nemeth et al. (WO 01/99703 A2), and further in view of Li et al (US 6,470,092 B1).

Yokoi discloses a method, comprising:

capturing a real-time in vivo images with a camera ("set of images captured inside the body"; Yokoi: col. 19, line 63-64); and relaying information on in vivo camera travel distance in GI tract (see col. 14, lines 57-67; col. 15, lines 1-5; data obtained are temporarily accumulated in memory located inside the capsule and then transmitted by the transmission-receiving circuit 30 and antenna 31 to a receiver such as the external unit 5 located outside the body by comparing the data obtained by the receiver with the standard values, and to determine the capsule advancing position or state).

Yokoi does not disclose automatically diagnosing an abnormality in a non-luminance generalized R and G color space in real-time in the in vivo images by comparing the images to abnormality feature templates using color image processing algorithms; and signaling an alarm in real-time when the abnormality is detected.

Adler, in the same field of endeavor, teaches diagnosing an abnormality in a non-luminance generalized R and G color space in real-time in the in vivo images using color image processing algorithms (see paragraph [0009], [0023], [0030], [0031]; detecting colorimetric

abnormalities in a gastrointestinal tract. The capsule includes an image-receiver for receiving images from the gastrointestinal tract, and a processor for generating a probability indication for presence of calorimetric abnormalities by comparing color content of the images to at least one reference value; Each test sample T is located within a coordinate system represented by the following variables: hue H, saturation S and value V. Hue H represents a number related to the dominant wavelength of the color stimulus, and varies from 0 to 1 as the color changes from red to yellow to green to cyan to blue to magenta and back to red again. Saturation S corresponds to color purity, and in the case of a pure color is equal to 100%. Value V is a measure of relative intensity of color, representing brightness of red, blue and green (RBG). A distance vector r(B,T) between test sample T and an ideal pathology sample B is calculated. Another distance vector r(R,T) between test sample T and a reference sample of healthy tissue R is calculated. The relationship of distance vector r(B,T) and distance vector r(R,T) is calculated. Each test sample T is classified based on the relationship between distance vector r(B,T) and distance vector r(R,T)).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the Yokoi reference to color image process/processing algorithms to the examination bundlette as suggested by Adler, in order to detect a colorimetric abnormality that may indicate a pathological condition, such as bleeding, blood clots, polyps, lesion, ulcerations, angiodisplasia, and telagecasia (see paragraph [0022]).

Nemeth, in the same field of "monitoring medical data" (Nemeth: pg. 1) teaches:

and signaling an alarm in real-time when the abnormality is detected ("analyze the medical data and provide the third party with an alert if the medical data meets the established conditions for an alert"; "provide alerts, warnings and other information to third party will be

informed, preferably in real time or near real time, of instances which the medical data meet certain predetermined conditions that merit the immediate attention of the third party; Nemeth: figure 2, numeral 58; pg. 32, lines 17-18; pg. 7, lines 24-28).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify Yokoi with Adler to automatically detect an abnormality and signal an alarm as suggested by Nemeth, in order "analyze and respond to the medical data in a timely matter" (Nemeth: pg. 8, lines 11) and to reduce human errors in manual detection.

Li, in the same field of medical abnormality detection in images (see col. 1, lines 15-18) teaches detecting an abnormality by comparing the image to abnormality feature templates (see col. 2, lines 3-28 obtaining templates and comparing the candidate abnormality with the templates).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the Yokoi, Adler with Nemeth combination to compare an image to abnormality feature templates as suggested by Li, to determine a "cross-correlation value" to determine whether an abnormality is malignant or benign (col. 2, lines 3-28).

***Conclusion***

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EDWARD PARK whose telephone number is (571)270-1576. The examiner can normally be reached on M-F 10:30 - 20:00, (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Samir Ahmed can be reached on (571) 272-7413. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Edward Park
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/Brian Q Le/
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